2.0 NON-TECHNICAL ABSTRACT

The abnormal proliferation of cells involved in the formation and growth of cancers is under the control of abnormal genes called oncogenes. A gene called E1A may be able to cause cancer cells to lose their malignant characteristics. The E1A gene is obtained from a small part of the DNA of a common virus and can be introduced with a gene delivery system composed of lipids (or fats) into cancer cells maintained in culture and into cancer cells in animal models. When administered to the tumor in an animal model of breast and head/neck cancers, the E1A Lipid Complex produced tumor growth inhibition and extension of survival of treated mice compared to untreated control mice.

An E1A Lipid Complex Phase I trial has been completed. Eighteen patients with head and neck squamous cell carcinoma (HNSCC) or breast cancer metastases to the chest wall were studied. In the Phase I study no serious side effects attributable to the injection of E1A into tumors were seen. The Phase II study described in this document will be conducted in patients with advanced metastatic or surgically unresectable HNSCC. In this study we will evaluate tumor response to see if the tumors shrink or disappear after injections of the E1A Lipid Complex. We will also measure the patient's quality of life and pain level compared to before receiving E1A injections and we will continue to look for possible side effects that may be related to the gene therapy.